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5/22/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445

Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 13, 1998 WL-31-S

WARNING LETTER

Mr. Chris A. Haudenschild
President
CliniComp International Inc.,
9655 Towne Center Drive
San Diego, CA 92121

Dear Mr. Haudenschild:

During an inspection of your firm conducted between March 31 to May 4, 1998, our investigator determined that your firm manufactures remote patient monitoring and data acquisition systems. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, and the facilities and controls used for the design manufacturing, packing, storage, or installations are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, control and maintain procedures for implementing corrective and preventive action(s), including requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems as required by 21 CFR 820.100(a)(1). For example, there was no analysis of manufacturing processes, sampling, and testing to identify and correct causes of recurring problems of electrical grounding in finished devices.

2. Failure to ensure device master records contain all required information as required by 21 CFR 820.181. For example, device master records for mini data acquistion systems and powered data acquistion systems do not include all the necessary information regarding the products specifications.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, California 92612-2445

Sincerely yours,

Elaine C. Messa
District Director

DER/jm

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7TH ST MS-357
P O Box 942732
Sacramento, CA 94234-7320